

### **Remarks**

Claims 1-43 were previously presented for the Examiner's review and consideration.

Applicant appreciates the courtesies extended to Applicant and his representatives, Paul Bianco and Gary Winer, during the telephonic interview conducted on April 29, 2008. The amendments and remarks presented herein reflect those discussed during the interview.

#### **Rule 131 Affidavit with Respect to Engh**

Applicant submitted a Declaration under 37 C.F.R. §131, having a mail room date of April 30, 2007, which, as described in an accompanying Response, established an invention date prior to the effective date of Engh. However, while reviewing the claims of the instant application, it became apparent to Applicant's representative that disclosure needed to support all of the claims in the current claim set may not be present as required in the supporting application referenced as Appendix "A" in the affidavit. Accordingly, Applicant must withdraw the Rule 131 Affidavit, and accordingly, respond to the current as well as previous rejection, mailed March 6, 2008. Applicant and Applicant's representative regret any inconvenience this has caused the Examiner.

#### **Priority Date**

Priority support for the current claim set may be found no later than in U.S. application Serial No. 10/191,751, filed July 8, 2002, cited in paragraph [0001] of the instant specification, which issued as U.S. Patent 7,104,996 on September 12, 2006.

#### **35 U.S.C. §103(a) Rejection**

In the Office Action mailed March 6, 2008, claims 1-7, 11-13, 15-28 and 30-43 were rejected as being unpatentable over MacArthur (6,342,075) ("MacArthur") in view of Engh et al. (6,482,209) ("Engh").

In the instant Office Action, claims 1-7, 11-13, 15-28 and 30-43 were rejected as being unpatentable over MacArthur in view of Coates et al. (5,100,409) ("Coates").

For reasons set forth below, Applicant respectfully submits that these rejections should be withdrawn.

MacArthur

MacArthur was discussed in detail in a previous response, and in the interest of brevity, that discussion is incorporated herein by reference.

In particular, MacArthur discloses a structure which includes two prosthetic components useful in *either* total *or* unicompartmental knee replacement of portion of the intercondylar notch and/or and the *medial and lateral* condylar surfaces of femoral condyles 22 and the tibial plateaus of tibial plateau 32. (c8,ln30-34, emphasis added).

Thus MacArthur teaches a total knee replacement, replacement of both condyles, or replacement of both condyles and a portion of the intercondylar notch. Fig's. 8B,C of MacArthur illustrate an incomplete surgery. The completed surgery is shown in Fig. 8D, in which two condyles are replaced, or in Fig. 9, which is a total knee replacement. Nowhere in MacArthur is it taught or suggested to replace the articulating surface of *only one* condyle as well as a portion of the trochlear section of the femur.

Considering the method of operation of MacArthur, it appears necessary to replace both condyles because the articulating surface on a condyle is raised by a plurality of pins. Accordingly, if the other condyle is not treated in a similar fashion, the knee angle (valgus/varus) would become distorted. Alternatively, modifications to the disclosure of MacArthur would be required, said modifications not being suggested or taught within the reference.

Other arguments made previously with respect to MacArthur additionally continue to apply. In particular, there are significant disadvantages and difficulties with respect to implanting and aligning numerous pins, as well as the establishment of numerous potential points of failure, and rough articulation, following implantation.

Eng

Eng discloses instrumentation to sculpt the articular surface of a first bone that normally articulates in a predetermined manner with a second bone. (Abstract). Implants provide intraoperative surgical options for articular constraint and for facilitating proper alignment and orientation of the joint to restore kinematics as defined by the individual patient anatomy. (Id).

Eng further discloses that a typical total knee joint replacement involves replacing the articular surfaces of the lateral femoral condyle 12, the medial femoral condyle 14, the medial tibial condyle 30 **and** the lateral tibial condyle 32. (c8,ln43-46). The femoral side may be resurfaced by **two or three** components and the tibial side may be resurfaced by two components or a unitary piece. (c5, ln16-19).

While Eng states that the implants are specifically designed to fit through minimally invasive incisions and incorporates any and all combinations of fixed and mobile bearing inserts or parts (c6,ln11-13), Eng only contemplates at least a replacement of both femoral condyles, as may be determined from the figures, and from the following excerpts from the specification:

The maximum number of components implanted would include femoral and tibial components for the lateral tibiofemoral compartment, femoral and tibial components for the medial tibiofemoral compartment and femoral and patellar components for the patellofemoral joint. (c6,ln62-67). Alternatively, the lateral femoral condyle and the patellar groove may be covered by a common implant. (Id).

Since right and left tibial baseplates **are required**, the same baseplate may be used for a mobile bearing medial insert and a fixed bearing lateral insert. (c14,ln4-7).

An **optional third** component 134 may be provided to resurface the femoral side of the patellofemoral joint. (c14,ln24-26).

The external tools used to guide the tibial cutter may provide relative alignment between the **medial and lateral resections**. (c9,ln59-61). Alternately,

the medial and lateral cavities in the tibial plateau may be *prepared simultaneously* by having two guide elements 49 linked together by a hinge that restrains the medial and lateral milling burrs 47 in a common plane. (Id).

The femoral cutter is designed to reference the tibial *resections* 50 and 52 when making the femoral *resections*. (c10,ln18-20).

As can be seen in Fig's. 39 and 41-42, and accompanying text in Col. 14, Engh discloses a combined condylar and patellofemoral component. However both condyles are replaced. There is no disclosure in Engh of a unilateral replacement, and further no disclosure or suggestion of the articulating surface of *only one* condyle and a portion of the trochlear groove being replaced.

#### Coates

Coates discloses a trial implant comprising a modular bracket defining a structure having an internal surface adapted to be seated on the distal aspect of a resected femur bone... (c2,ln6-9). The bracket has an elongated central opening appointed to expose the resected surface of the femur, including means for guiding a tool along a predetermined path for controlled shaping of a patellar groove in the surface exposed through the opening. (Id). A replaceable insert covers the opening and articulates with a proximal aspect of the tibia for interoperative trial reduction of the knee joint, whereby prior removal of the bracket from the resected bone is unnecessary following shaping of the patellar groove.

Coates further discloses a device and method of using the device by which a patellar groove may be shaped in a resected femur by instrumentation which also functions as a trial condylar implant during trial reduction *of the total knee joint*. (c2,ln43-57).

Thus Coates does not disclose or suggest an implant to remain in the body, as is claimed. Coates is directed solely to a trial component, removed before the end of surgery and never intended to serve as an articulating surface, but rather only as a measuring tool. A trial component does not bear weight or remain within the body after surgery, and thus Coates

represents distinctly non-analogous art. Further, any weight borne during trial fitment is incidental and entirely unrelated to weight bearing in the context of an implant.

Additionally, Coates further does not disclose a unicondylar implant, and particularly, does not disclose or suggest replacement of only one condyle and a portion of the trochlear groove.

Thus, none of the references disclose or suggest the claimed elements, as is claimed in claims 1 and 43 of, *inter alia*, an implant having a first member operative as a weight bearing surface through the normal range of motion of the joint for only one condyle, and a second member including a second articulating surface affixable to a trochlear section of the femur.

Method claims 12 and 27 contain analogous recitations.

As a combination of Engh, MacArthur, and Coates do not disclose or suggest all claimed elements as claimed in independent claims 1, 12, 27, and 43, Applicant respectfully submits these claims are allowable over the cited references. As claims 2-7, 11, and 42 depend from claim 1; claims 13 and 15-26 from claim 12; and claim 28 and 30-41 from claim 27, these dependent claims necessarily include all the elements of their base claims. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejection.

Applicant(s): P. Bonutti  
Application No.: 10/727,290  
Examiner: P. Philogene

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-012D).

Respectfully submitted,

/Gary S. Winer/

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